K070260 P1/2

FEB 23 2007

9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Denise Haley
Sr. Quality & Regulatory Engineer
Ultrasound & Monitoring Systems
Philips Medical Systems
3000 Minuteman Road, MS0240
Andover, MA 01810-1099

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This summary was prepared on 24 January 2007

2. The name of this device is the Philips ST/AR ST and Arrhythmia Software, Release H.0. Classification names are as follows:

Classification	ProCode	Description
870.1025, II	74 MLD	Monitor, ST Alarm
870.1025, II	74 DSI	Arrhythmia Detector and Alarm
None	74 MHX	Physiological Monitor, Patient Monitor

3. The new device is substantially equivalent to the previously cleared ST/AR ST and Arrhythmia Software device marketed pursuant to K964122, K991773, K001348, K003621, K014261 and K021251 and the Philips 2010 Plus Holter for Windows K010949.

4. The modification is a software-based change that adds QT/QTc interval monitoring features.

5. The new device has the same Indications for Use and Intended Use as the legally marketed predicate devices.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that ST/AR Release H.0 meets all defined reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2007

Philips Medical Systems
Ms. Denise Haley
Sr. Quality and Regulatory Engineer
3000 Minuteman Road
Andover, MA 01810

Re: K070260
Trade Name: Philips Medical Systems ST/AR ST and Arrhythmia Software, Release H.0
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST measurement and alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: January 24, 2007
Received: January 26, 2007

Dear Ms. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications Statement

Indications for Use

510(k) Number (if known): K070260

Device Name: ___ ST/AR ST and Arrhythmia Software _____

Indications for Use:

Where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

The intended use of the ST/AR cardiotach is to monitor a neonatal, pediatric, or adult patient's ECG for heart rate and produce events/alarms for one or two ECG leads. The cardiotach function is capable of monitoring both paced and non-paced patients.

The intended use of the ST/AR arrhythmia analysis algorithm is to monitor a neonatal, pediatric, or adult patient ECG's for heart rate and ventricular arrhythmias and produce events/alarms for one or two ECG leads. The arrhythmia analysis algorithm is capable of monitoring both paced and non-paced patients.

The intended use of the ST/AR ST analysis algorithm is to monitor an adult patient's ECG for ST segment elevation or depression and produce events/alarms for all possible ECG leads. The ST analysis algorithm is capable of monitoring paced and non-paced adult patients.

Note: The ST algorithm does not analyze ventricularly paced or ventricular ectopic beats.

The intended use of the ST/AR QT/QTc analysis is for use by the physician in the risk assessment process indicated for neonatal, pediatric and adult patients with and without symptoms of arrhythmia. QT measurement is intended to be used by qualified health professionals in hospital or clinical environments. Composite QT (single or multi-lead derived) measures the interval only and is not intended to produce any interpretation or diagnosis of those measurements.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K070260